

Warnings and Instructions: Design Factors for Medical Devices and Systems

Michael J. Kalsher
Department of PP&CS
Rensselaer Polytechnic Institute
Troy, NY 12180-3590 USA

Michael S. Wogalter
Department of Psychology
North Carolina State University
Raleigh, NC 27695-7801 USA

Abstract

The development and widespread use of sophisticated medical devices to help patients has also hurt patients through operator error. Some of this error may be attributable to the quality of the labeling instructions that accompany these devices. Lessons learned from two decades of research on warnings may serve as a guide to development of effective medical device labeling practices. In this article, we highlight some of the issues associated with poor medical device labeling practices, suggest a framework for guiding development of medical device labeling practices based on the communication-human information processing model, and finally, present an example of a medical device for which better labeling and instructions are needed.

Introduction

Recent advancements in science and technology have led to a rapid proliferation of medical devices. The widespread availability of presumably helpful medical products and devices is being welcomed enthusiastically by health care providers and the general public. The presence of technological sophistication, unfortunately, does not necessarily equate with increased safety. The specific area of use (e.g., in hospitals or private homes) and characteristics of the intended user (e.g., doctor or other health-care provider, patient) must be carefully considered. Because of the substantial differences in operators and settings, a device that may be useful in one situation may introduce considerable risk during use in another (e.g., in the home). Indeed, even experienced highly trained individuals can make mistakes when involved in heavy workload conditions (e.g., Weinger, Herndon, Paulus, Gaba, Zornow, & Dallen, 1994). Under such conditions, operators of medical devices might only have time to glance at instructions or warning labels, and if those materials are poorly designed they may encode little or nothing about them. In a sense, the development of sophisticated medical devices intended to help people can, under certain conditions, actually harm them.

One reason for concern is that medical devices have become increasingly complex, and they can be

more difficult to operate. How they work, their composition, and the hazards associated with their use are not always readily apparent. Also, many devices have potential hazards that have not been eliminated through design or guarding. Unfortunately, the rapid advances in medical technology have not been paralleled by efforts to calibrate the demands these devices place on the physical and cognitive abilities (and limitations) of the people who will use them. Aside from healthcare professionals who may have some formal training on the device, other users may not have the knowledge and skills needed to operate these devices properly.

In the absence of training, well-designed labels and instructional materials might help mitigate the risks associated with (the use of) medical devices. However, the instructional labels and warnings that accompany these devices, if they are available, are frequently designed and/or written poorly, and therefore fail in their intended purpose of communicating the information needed for their proper and safe operation. The U.S. Food and Drug Administration (FDA) requires thorough safety and effectiveness testing of new medical devices. In light of current contextual factors—increasingly complex medical devices and their widespread availability to users of all types—ensuring safe use of medical devices may require formal usability testing (see e.g., Wogalter, Conzola, & Vigilante, 1999).

Research concerning the design of instructions and warnings that has evolved over the past two decades (see Wogalter, 1999) may hold great promise for helping people to understand what they need to know to avoid the non-apparent hidden or latent hazards associated with the use of medical devices.

Applying Warnings Research to Develop More Effective Medical Device Labeling Practices

The urgent need for refined instructional warning labels on medical devices is a relatively new phenomenon. Until recently, manufacturers could reasonably assume that the use of most complex medical devices would be restricted to highly trained medical personnel, such as physicians, anesthesiologists, nurses, and emergency medical technicians, to name a few. However, the increased demand for medical equipment designed for in-home use by members of the general public has dramatically altered the range of sophistication of potential operators. Although the specific design requirements for instructional warnings for medical devices may differ somewhat from the design characteristics for other applications (and these characteristics will be discussed more extensively later in this article), the overall goals and principles are the same.

There are two primary goals of warnings (Wogalter & Laughery, 1996). One is to inform people about potential hazards so they have an appreciation of what could happen. The second, and perhaps most important, goal is to change behavior, or in other words, to redirect people away from performing unsafe acts that they might otherwise do without the warning.

One guiding structure for development of instructional warnings that meets the goals just described is the model proposed by Wogalter, DeJoy, and Laughery (1999) termed the Communication Human Information Processing model, or C-HIP. As shown in Figure 1, this modeling approach categorizes people's mental activities into a linear sequence of information processing stages and recognizes the importance of several other precursors, including characteristics of the source of the information and the medium (or channel) by which this information is conveyed. According to the C-HIP model, the process starts with the warning information moving from a source (e.g., a device manufacturer, the FDA) through some channel (e.g., an on-product instructional

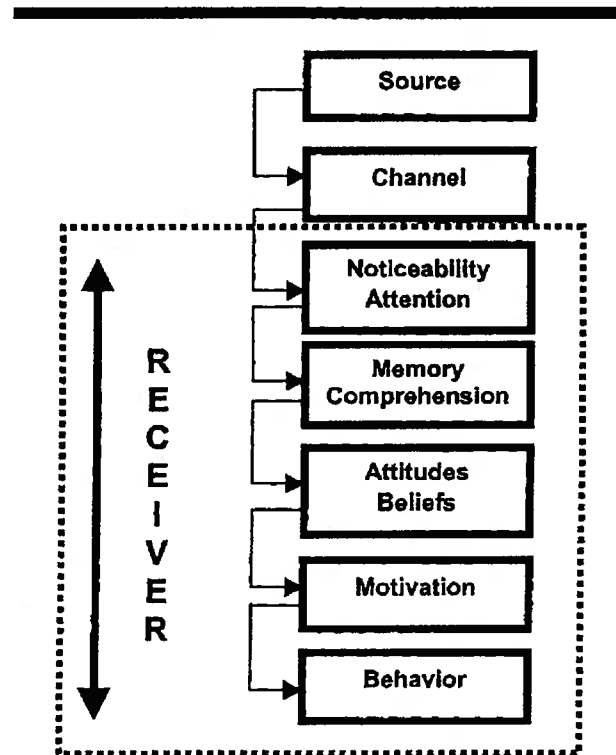


Figure 1. The Communication Human Information Processing (C-HIP) Model.

label) to arrive at the receiver. The receiver must then notice and attend to the information. Once it has been attended to, it must be understood, and the information, must, in turn, be consistent with the person's attitudes and beliefs. Motivation is the last stage before behavior is achieved. Sufficient motivation must be present—or induced—to produce the appropriate behaviors.

Each stage of the model can produce a bottleneck preventing information from being processed further. Accordingly, the model predicts that a label that lacks a coherent message from the source, is not conveyed by an adequate channel, and is not congruent with receiver characteristics will not be noticed or read. A label that is not read will have little or no influence on beliefs and attitudes, and a poorly understood label will probably not motivate the appropriate precautionary behavior.

The C-HIP Model as an Investigative Tool

Wogalter et al. (1999) have suggested that the C-HIP model may be a particularly useful

investigative tool for helping researchers to discover why warnings do not fulfill their goal of promoting safe behavior. Applied to medical devices, this suggests that when people do not use these devices properly (safely), the C-HIP model can be used diagnostically to determine whether misuse of the device can be linked to the instructional label, and if so, the specific feature(s) and content of the label in need of improvement.

For example, an investigation that follows the linear sequence proposed by the C-HIP might first assess the characteristics of the message source. Obviously, if there is no source then there will be no message. But given that the message has a source, is the channel of communication appropriate and effective in influencing the receiver? If not, other media should be used. Investigation may reveal that the source of the message and the medium through which the message is conveyed are appropriate, but that the instructional label that accompanies a particular medical device lacks sufficient salience. In other words, the label may not attract the operator's attention. In this instance, one possible solution is to add or change features to increase the warning's conspicuity. However, it is also possible that the device's instructional label might have failed not because of deficiencies in these preceding stages, but because the operator did not comprehend its intended meaning. In this instance, making the warning more understandable might alleviate the problem.

Another possible explanation for a low rate of compliance behavior may be traceable to discordant attitudes and beliefs with respect to the message being conveyed. In such cases, the obstacle is at the beliefs and attitudes stage. When such differences in beliefs and attitudes exist, the warning needs to be sufficiently persuasive to convince these individuals to take note of and heed the warning.

Lastly, an instructional label may be physically apparent, understandable, and consistent with beliefs and attitudes, but it still might not be behaviorally effective if it does not motivate people who operate medical devices to exert the effort to comply with it. In such situations, the warning might be inadequate in terms of conveying how badly they or others could be hurt, or because it requires more effort than people are willing to expend in this particular situation. Beliefs or expectations about threat provide much of the initial motivation for compliance, but compliance is ultimately a cost-benefit decision, in which the

benefits of compliance (typically injury prevention) are weighed against the costs or barriers associated with performing the indicated precautions.

Thus, the C-HIP model can help pinpoint the reasons why an instructional label or warning failed to produce the desired end result of safe and effective operation of the medical device. With knowledge of the factors that influence each stage of the model, and a little detective work, the aspects that need to be corrected are more readily determined than without this framework.

The Need For More Effective Medical Device Labeling Practices: An Example

The rapid proliferation of medical devices has created an urgent need for better labeling practices. This is particularly true for devices designed for at-home use. Clearly, the best strategy would be to eliminate the hazards associated with these products completely through design or guarding. However, since these approaches are not always possible, people who use these devices may be forced to rely upon the instructions and warning labels that accompany these devices. Unfortunately, the information that accompanies medical devices is frequently defective and may actually increase the chances that people will be injured. One example is the digital thermometers currently available for home use, typically with children.

One problem with devices like thermometers is that most people do not believe that their use can lead to injury, so in a sense, the hazards are non-obvious or "hidden." One of the most significant dangers posed by digital thermometers is the possibility they will provide inaccurate temperature readings, which in turn, can lead patients and their caregivers to make erroneous assumptions and poor decisions. Many of the factors that affect the accuracy of digital thermometers are known, but this information does not always reach the user because the manuals are often lengthy (more than 20 pages long in some instances), they are poorly organized, and some of the most critical patient safety information is obscured by their placement in the middle of the manual. In addition, these materials often contain potentially confusing or contradictory information, as in the following sample instructions taken directly from a currently popular brand of digital ear thermometer:

NOTE: In the following situations, it is recommended that you take three temperatures in the same ear. If they differ, use the highest reading:

- (1) Infants in the first 90 days of life.
- (2) Children under three years of age who have a condition such as a compromised immune system and for whom the presence or absence of fever is critical.
- (3) When you are first learning to use the ear thermometer until you are comfortable with the technique and are obtaining consistent readings.

No more than three readings should be taken consecutively in the same ear since repeatedly inserting the cool thermometer into the ear canal can lower the reading.

Other factors known to affect the accuracy of digital thermometers include: (1) the use (or nonuse) of filter caps on the thermometer probe; (2) the presence of excessive ear wax; and (3) the patient's position just prior to obtaining a temperature reading (taking a temperature in the ear of someone who has been lying down drives up the temperature). Clearly the procedures and factors involved are much more complex than most people expect. If people remain unaware of these issues, it increases the chances that they will make erroneous decisions.

Recommendations based on the C-HIP model could dramatically improve the effectiveness of these materials and might include the following suggestions. With respect to the first stage, the attributed source (the manufacturer) is probably appropriate, although the FDA or Surgeon General are also possible choices (Wogalter, Kalsher, & Rashid, 1999). The channel might be improved by placing the most important information as a label directly on the product. Information might also be improved with the use of supplemental media such as audio or videocassette instruction. The receiver is more likely to notice the most critical print warning if they are enhanced with salience features (e.g., color) and placed at locations where the user would likely glance. This might be accomplished by placing safety critical information directly on the exterior packaging, moving other important instructional information to the front sections of the manual, and increasing the conspicuity of these facts. Understandability could be enhanced by including relevant content, in short statements, and in simple language. Strong, persuasive statements may be required to change incorrect beliefs; for example, convincing people that taking an accurate reading involves many more factors than they might expect. Keeping the effort required to carry out the procedures reasonably low will increase the chances that the proper behavior will be performed. Testing and, in particular, usability testing would help determine what stages are most likely to be causing

bottlenecks and what kinds of enhancements would be most beneficial.

Although there are many other ways in which the ear thermometer instructions can be improved, the point is that better labeling is an important facet in preventing the possibility of under-or-over medicating, or ensuring that people take the correct actions, such as seeking the advice of a physician when it is warranted.

Conclusions

Although manufacturers must demonstrate the effectiveness and safety of new devices entering the U.S. market, the same efforts are not currently being applied to product instructions and labels. They instead appear to be an afterthought. The quality of the instructions can significantly affect the device's effectiveness and safety. According to Tort law (2nd Restatement, 1965), warnings and instructions are part of the product, and if they can be shown to be defective, then the product is defective. Now that medical devices are being used by non-trained medical personnel, the learned intermediary doctrine that protects manufacturers from liability may no longer be applicable. To establish the adequacy and effectiveness of labeling, usability studies must be performed to protect the safety of people and protect manufacturers in any eventual lawsuits (which should reduce in frequency with better labeling). There are methods, research, and theory in the human factors discipline that are available to address and improve medical device labeling.

References

- Restatement (Second) of Torts, § 402A (1965).
- Weinger, M. B., Hemdon, O. W., Paulus, M. P., Gaba, D., Zornow, M. H., & Dallen, L. D. (1994). Objective task analysis and workload assessment of anesthesia providers. *Anesthesiology*, 80, 77-92.
- Wogalter, M. S. (1999). Factors influencing the effectiveness of warnings (pp. 93-110). In H. J. G. Zwaga, T. Boersema & H. C. M. Hoonhout (eds.), *Visual information for everyday use: Design and research perspectives*. London: Taylor & Francis.
- Wogalter, M. S., Conzola, V. C., & Vigilante, W. J. (1999). Applying usability engineering principles to the design and testing of warning messages. *Proceedings of the Human Factors and Ergonomics Society*, 43, 921-925.
- Wogalter, M. S., DeJoy, D. M., & Laughery, K. R. (1999). Organizing theoretical framework: A consolidated communication-human information processing (C-HIP) model (pp. 15-23). In M. S. Wogalter, J. W. Brelsford, D. M. DeJoy, and K. R. Laughery (Eds.), *Warnings and Risk Communication*. London: Taylor and Francis.
- Wogalter, M. S., Kalsher, M. J., & Rashid, R. (1999). Effect of signal word and source attribution on judgments of warning credibility and compliance likelihood. *International Journal of Industrial Ergonomics*, 24, 185-192.
- Wogalter, M. S., & Laughery, K. R. (1996). WARNING: Sign and label effectiveness. *Current Directions in Psychology*, 5, 33-37.